MAR 2 2 2006

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K060451

1. Submitter's Identification:

VuComp, Inc.
6509 Windcrest Drive, Suite 160
Plano, Texas 75024

Contact: Mr. Stuart Barab
Tel: 1-888-266-7462 (Ext.121)
email: stuart.barab@vucomp.com

Date Summary Prepared: January 27, 2006

2. Name of the Device:

M-Vu™ Viewer Station

3. Predicate Device Information:

Second Look® Viewer, K#042697, ICAD, Inc., Beaver Creek, Ohio

4. Device Description:

The M-Vu™ Viewer Station is a computer-based system that displays digitized, low-resolution, radiographic information. The system is typically used to support a radiologist's review of screening and/or diagnostic mammograms. The system has two main functional components: a commercially available computer with an integrated LCD display and an attached bar code reader. The computer is connected to the M-Vu™ CAD Station via an Ethernet network to download selected radiographic images and Computer-Aided Detection (CAD) results or other annotations. The Viewer Station serves no other purpose than providing convenient viewer support.

The Viewer Station has built-in menu-driven options to allow the technician or radiologist to customize the system in several ways. Among these ways are:

1. The Viewer Station image display can be changed to match the hanging protocol preferred by the reviewing radiologist.
2. The patient ID information can be toggled on or off.
3. The CAD Marks can be toggled on or off.
4. The marked regions-of-interest can be magnified two levels.
5. The user can request printed reports with or without CAD results shown.

5. Intended Use:

The M-Vu™ Viewer Station is intended to be used to display low resolution, non-diagnostic medical images with annotations such as pre-computed regions of interest or pre-computed CAD marks.

6. Comparison to Predicate Devices:

Similarities and Differences are as follows:

- The predicate device uses a touch screen display to allow user interface to the system. The M-Vu device uses a mouse instead. Both are standard user interface applications and represent no functional difference between the devices.
- Both devices offer a magnify feature. The predicate device allows the user to select images using the touch screen and the M-Vu device uses a mouse.
- The predicate device allows direct printing on screen to a network printer. The M-Vu device allows printing over the network to a M-Vu CAD Station printer and the user can select to have the CAD results superimposed on the low resolution image or not.
- The predicate device allows the user to view pre-computed ultrasound results. The M-Vu device does not offer this feature.

In summary, both the subject and predicate devices are the same or very similar in significant aspects including the intended use of the devices.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the M-Vu™ Viewer Station device in the intended environment of use is supported by testing that was conducted for safety and performance, including software validation and verification testing. Results of the testing revealed that the M-Vu™ Viewer Station is substantially equivalent to the predicate device.

8. Discussion of Clinical Tests Performed:

Not applicable

9. Conclusions:

The M-Vu™ Viewer Station device has the identical intended use and similar characteristics as the predicate device. Moreover, software testing contained in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the M-Vu™ Viewer Station device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2006

VuComp, Inc.
% Ms. Susan D. Goldstein-Falk
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd. Suite 200
GREAT NECK NY 11021

Re: K060451
Trade/Device Name: M-Vu™ Viewer Station
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 10, 2006
Received: February 21, 2006

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit B

Indications for Use

510(k) Number (if known): K060451

Device Name: M-Vu™ Viewer Station

Indications For Use:

The M-Vu™ Viewer Station is intended to be used to display low resolution, non-diagnostic, medical images with annotations such as pre-computed regions-of-interest or pre-computed CAD marks.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) OR Over-The Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060451